National Institute of Allergy and Infectious Diseases / Division of Microbiology and Infectious Diseases	**Policy** **DMID Clinical Research Policy Development, Review and Approval for NCRS Documents**	No: DMID.POLDEV.001
	Approval Date: 21-July-2008 Effective Date: 01-August-2008	Version: 1.0

1.0 Purpose:

This policy describes the development process for approval and distribution for NIAID Clinical Research Standards (NCRS) policies and procedural documents affecting DMID-supported clinical research operations.

2.0 Scope:

2.1 This policy applies to clinical research policies and associated documents affecting DMID-supported clinical research operations, exclusive of Branch-specific documents, and developed in compliance with NIAID Clinical Research Standards.

1. Clinical Research Development, Review, Conduct and Oversight;
2. Clinical Research Management;
3. Training and Education; and
4. Quality Assurance/Quality Control.

The scope of these standards includes all clinical research activities as defined by the 1995 NIH Director's Panel on Clinical Research.

2.2 Division of Microbiology and Infectious Diseases (DMID) staff are responsible for adhering to applicable DMID policies and procedures affecting the oversight of DMID-supported clinical research.

3.0 Background:

In 2005, the Director of NIAID, Dr. Fauci, created the Sullivan Working Group to respond to adverse perceptions regarding regulatory processes of DAIDS-supported clinical research. In response to the Sullivan Report, NIAID established the NIAID Clinical Research Subcommittee (NCRS) of the NIAID Executive Committee. NCRS looks for harmonization opportunities of policies and an exchange of best practices across NIAID divisions.

NCRS identified universal principles that should be addressed within each division, e.g., every division should have an identified employee reporting directly to the Division Director, who would be charged with the responsibility of ensuring that NIAID-sponsored clinical trials are "conducted in compliance with all applicable regulations and requirements for the safety of the patient and the integrity of the trial." In order to give each division the flexibility to implement NIAID policies according to its own needs, the subcommittee intentionally chose a decentralized approach with stronger, centralized oversight.

DMID polices generated with appropriate input from involved staff are a way for DMID to achieve the NIAID Clinical Research Standards.

4.0 Definitions:

Clinical Research: Per the NIAID definition, patient-oriented research, including epidemiologic and behavioral studies, outcomes research, and health services research; research on mechanisms of human disease, therapeutic interventions, clinical trials, and development of new technologies, not including in-vitro studies using human tissues not linked to a living individual.

DMID Clinical Research Policy Development Core Team Members: Comprised of representatives for OCRA, ORA and DMID Program Branches/Offices, and facilitated by a coordinator. (See section 5.0 Responsibilities)

Document cycle: The development through approval cycle target is 3 months for all proposed DMID NCRS policies and procedural documents from the first planning meeting through approval. This process is repeated for the annual review of DMID NCRS policies.

NIAID Clinical Research Standards (NCRS): Standards for best practices across NIAID divisions established from the *Findings and Recommendations: Sullivan Working Group on DAIDS Regulatory Activities*, August 2005. The scope of these standards is reflected in the 1995 NIH Director's Panel on Clinical Research, which defines requirements for maximizing the quality of NIAID clinical research, and provides flexibility to account for the diverse contexts in which NIAID research is conducted.

Policy: A plan to guide decisions and actions.

Project Officer: A DMID staff member who coordinates the substantive aspects of a contract from planning the request for proposal to oversight.

Standard Operating Procedure: Instructions and methods used for a specific process or situation.

Subject Matter Experts: Individuals in NIAID who are consulted for specific guidance to optimize the development of applicable DMID NCRS policies and procedures.

5.0 Responsibilities:

Role	Responsibility
DMID Policy Development Coordinator	• Policy team member • Meeting coordinator • Oversees drafts and revisions to policy documents / packages throughout the cycle of origination to annual review • Tracks document cycle
DMID Policy Development Core Team Members: Representatives from ORA, OCRA , Program Branches/Offices and Associate Director of Clinical Research	• Contribute to the origination and development of polices and procedures applicable to internal and external DMID-supported operations • Ensure consistency across documents • Consider impact to current division workload and capacity • Identify need for and name • Subject Matter Experts • Coordinate feedback from additional Office and Branch reviewers • Provide final determinations around DMID policies and procedures, necessary to support internal and external DMID-supported operations
DMID Policy Development Ad-Hoc / Subject Matter Experts	• Advisory to core team members, providing guidance for specific areas of expertise

6.0 Implementation:

6.1 Policy Development Cycle (projected cycle 3 months):

6.1.1 Assessment and Planning: DMID Core Team Members meet to determine and plan policy needs

6.1.2 Ad-Hoc or Subject Matter Experts (SME) are consulted to provide guidance for specific areas of expertise

6.1.3 Draft / Review / Revision: Once a policy and /or procedural document need is determined, 2 draft cycles are implemented and reviewed by each representative.

6.1.3.1 Core Team Members are responsible for disseminating policies to their Branch/Office members and Branch Chiefs and Office Directors for review and for collection of comments.

6.1.3.2 Each Branch/Office is responsible for developing their respective work processes in compliance with DMID policies.

6.1.4 Final: Prior to release of the policy, DMID Core Team Members meet to review final policy and associated documents for content, agreement and plan for training and distribution.

6.1.5 Approval: Signature obtained from the Associate Director of Clinical Research.

6.2 Policy Release

6.2.1 Division announcement:

6.2.1.1 DMID Management Team Meeting

6.2.1.2 Division email announcement with attached policy

6.2.2 Project Officers will notify contract sites of release of applicable new/updated policies and procedural documents.

6.2.3 Internet / Intranet / Contractor posting, as applicable:

6.2.3.1 DMID internal processes will be posted to the DMID intranet

6.2.3.2 Policies and procedures affecting clinical research sites conducting DMID-supported clinical research will be posted to the DMID Clinical Trials Management website, and the NIAID/DMID Internet, as applicable

6.3 Training

6.3.1 Training needs will be assessed by the DMID Policy Development Core Team per DMID NIAID Clinical Research Standards, Version 1.0 – January 25, 2007, Standard 3.1.

6.4 Policy Evaluation

6.4.1 Initial policies and associated documents will be evaluated for feasibility beginning 6 months from the initial release date.

6.4.2 All policies and associated documents will be evaluated annually for effectiveness, and to ensure they remain current with new and revised NIH/NIAID policies and applicable federal regulations governing DMID-supported clinical research. This review timeline repeats the policy development cycle of 3 months.

7.0 References:

7.1 NIAID Clinical Research Standards

8.0 Inquiries:

8.1 For information or comments regarding DMID Policy Development, please contact NIAID DMID Policy Development Team

8.2 For information regarding meeting schedules and document coordination, please contact Claudia Baxter, RN, BSN, baxterc@niaid.nih.gov

9.0 Availability:

9.1 This policy is posted electronically:
- NIAID Internet DMID Clinical Research Policies webpage.
- DMID Intranet (DMID staff only)

10.0 Change Summary:

Version number	**Date of Revision: DD/MMM/YYYY**	**Replaces**	**Effective Date: DD/MMM/YYYY**	**Description of Revision/Retirement**
1.0	NA	NA	NA	NA
		1.0		